

AMENDMENTS TO THE CLAIMS

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40. (New) A method for forming a flocculated suspension of megestrol acetate, comprising:

combining micronized megestrol acetate and a composition containing a wetting agent,

wherein the wetting agent is present in an amount such that about 90% of the floccules of megestrol acetate have a diameter of less than 12 to 50 microns, and

wherein the flocculated suspension does not simultaneously contain polysorbate and polyethylene glycol.

41. (New) The method of claim 40, wherein about 90% of the floccules have a diameter of less than 21 to 50 microns.

42. (New) The method of claim 40, wherein about 90% of the floccules have a diameter of less than 28 to 50 microns.

43. (New) The method of claim 40, wherein the wetting agent composition further comprises a suspending agent.

44. (New) The method of claim 40, wherein the wetting agent is docusate sodium.

45. (New) The method of claim 40, wherein the wetting agent is a polyoxyethylene wetting agent.

46. (New) The method of claim 44, wherein the docusate sodium is present in the flocculated suspension in an amount of about 0.01 to about 0.04% w/w.

47. (New) The method of claim 40, wherein the wetting agent composition further comprises a polyhydric alcohol.

48. (New) The method of claim 47, wherein the polyhydric alcohol is glycerol.
49. (New) The method of claim 43, wherein the suspending agent comprises a hydrocolloid material.
50. (New) The method of claim 49, wherein the hydrocolloid material comprises a material selected from the group consisting of xanthum gum, hydroxypropyl cellulose, and carboxymethyl cellulose.
51. (New) The method of claim 50, wherein the hydrocolloid material is xanthum gum.
52. (New) The method of claim 40, wherein the wetting agent composition further comprises a buffer.
53. (New) The method of claim 52, wherein the buffer comprises a material selected from the group consisting of sodium citrate and citric acid.
54. (New) The method of claim 40, wherein the wetting agent composition further comprises a preservative.
55. (New) The method of claim 54, wherein the preservative is sodium benzoate.
56. (New) The method of claim 40, wherein megestrol acetate is present in the flocculated suspension in an amount of about 40 mg/ml.
57. (New) The method of claim 40, further comprising mixing the combined megestrol acetate and wetting agent composition.
58. (New) The method of claim 40, further comprising preparing the wetting agent composition by mixing the wetting agent with a suspending agent.
59. (New) The method of claim 58, wherein the mixing occurs for at least one hour.

60. (New) The method of claim 58, wherein the mixing occurs at a temperature of about 55 to about 75 °C.

61. (New) The method of claim 58, wherein the mixing is performed under vacuum.

62. (New) The method of claim 58, wherein the suspending agent is added through the bottom of a vessel containing the wetting agent.

63. (New) The method of claim 58, further comprising cooling the wetting agent composition.

64. (New) The method of claim 63, further comprising mixing while cooling.

65. (New) The method of claim 63, wherein cooling is continued down to about 25 °C.

66. (New) The method of claim 63, further comprising cooling the wetting agent composition to a temperature of about 25 to about 30 °C.

67. (New) The method of claim 63, wherein the megestrol acetate is combined with the cooled wetting agent composition.

68. (New) The method of claim 40, further comprising combining megestrol acetate under vacuum to the wetting agent composition.

69. (New) The method of claim 40, further comprising adjusting batch weight.

70. (New) The method of claim 40, further comprising combining a polyalcohol with the wetting agent composition.

71. (New) The method of claim 70, wherein the polyalcohol is added while maintaining the wetting agent composition at temperature of about 60 °C to about 70 °C.

72. (New) The method of claim 40, further comprising screening the combined megestrol acetate and wetting agent composition.

73. (New) The method of claim 40, further comprising straining the combined megestrol acetate and wetting agent composition.

74. (New) The method of claims 40, wherein the megestrol acetate is combined with the wetting agent composition at a pressure of about 7 to about 10 psi.

75. (New) A method for forming a flocculated suspension of megestrol acetate, comprising:

combining micronized megestrol acetate and a composition containing docusate sodium,

wherein the docusate sodium is present in an amount such that about 90% of the floccules of megestrol acetate have a diameter of less than 28 to 50 microns, and

wherein the flocculated suspension does not simultaneously contain polysorbate and polyethylene glycol.

76. (New) The method of claim 75, wherein the docusate sodium composition further comprises a suspending agent.

77. (New) The method of claim 75, wherein the docusate sodium is present in the flocculated suspension in an amount of about 0.01 to about 0.04% w/w.

78. (New) The method of claim 75, wherein the wetting agent composition further comprises a polyhydric alcohol component.

79. (New) The method of claim 78, wherein the polyhydric alcohol consists of glycerol.

80. (New) The method of claim 76, wherein the suspending agent comprises a hydrocolloid material.

81. (New) The method of claim 80, wherein the hydrocolloid material comprises a xanthan gum.

82. (New) The method of claim 75, wherein the docusate sodium composition further comprises a buffer.

83. (New) The method of claim 82, wherein the buffer comprises sodium citrate and citric acid.

84. (New) The method of claim 75, wherein the docusate sodium composition further comprises a preservative.

85. (New) The method of claim 84, wherein the preservative is sodium benzoate.

86. (New) The method of claim 75, wherein megestrol acetate is present in the flocculated suspension in an amount of about 40 mg/ml.

87. (New) The method of claim 75, further comprising mixing the combined megestrol acetate and docusate sodium composition.

88. (New) The method of claim 75, further comprising preparing the docusate sodium composition by mixing the docusate sodium with a suspending agent.

89. (New) The method of claim 88, wherein the mixing occurs for at least one hour.

90. (New) The method of claim 88, wherein the mixing occurs at a temperature of about 55 to about 75 °C.

91. (New) The method of claim 88, wherein the mixing is performed under vacuum.

92. (New) The method of claim 88, wherein the suspending agent is added through the bottom of a vessel containing docusate sodium.

93. (New) The method of claim 75, further comprising cooling the docusate sodium composition.

94. (New) The method of claim 93, further comprising mixing while cooling.

95. (New) The method of claim 94, wherein cooling is continued down to about 25 °C.

96. (New) The method of claim 93, further comprising cooling the docusate sodium composition to a temperature of about 25 to about 30 °C.

97. (New) The method of claim 93, wherein the megestrol acetate is combined with the cooled docusate sodium composition.

98. (New) The method of claim 75, further comprising combining megestrol acetate under vacuum to the docusate sodium composition.

99. (New) The method of claim 75, further comprising adjusting batch weight.

100. (New) The method of claim 75, further comprising combining a polyalcohol with the docusate sodium composition.

101. (New) The method of claim 100, wherein the polyalcohol is added while maintaining the docusate sodium composition at temperature of about 60 °C to about 70 °C.

102. (New) The method of claim 75, further comprising screening the combined megestrol acetate and docusate sodium composition.

103. (New) The method of claim 75, further comprising straining the combined megestrol acetate and docusate sodium to remove undissolved solids.

104. (New) The method of claim 75, wherein the megestrol acetate is combined with the docusate sodium composition at a pressure of about 7 to about 10 psi.

105. (New) A method for forming a flocculated suspension of megestrol acetate, comprising:

preparing a first composition containing a docusate sodium wetting agent, a suspending agent, a buffer, and a preservative,

preparing a second composition containing micronized megestrol acetate,

combining the first and second compositions to form a flocculated suspension of megestrol acetate such that about 90% of the floccules of megestrol acetate have a diameter of less than 28 to 50 microns, and

wherein the flocculated suspension does not simultaneously contain polysorbate and polyethylene glycol.

106. (New) The method of claim 105, wherein the docusate sodium is present in the flocculated suspension in an amount of about 0.01 to about 0.04% w/w.

107. (New) The method of claim 105, wherein the first composition further comprises one polyhydric alcohol component.

108. (New) The method of claim 107, wherein the polyhydric alcohol component consists of glycerol.

109. (New) The method of claim 105, wherein the suspending agent comprises xanthum gum.

110. (New) The method of claim 105, wherein the buffer comprises sodium citrate and citric acid.

111. (New) The method of claim 105, wherein the preservative is sodium benzoate.

112. (New) The method of claim 105, further comprising mixing the combined first and second compositions.

113. (New) The method of claim 105, further comprising preparing the first composition by mixing the docusate sodium with xanthum gum.

114. (New) The method of claim 113, wherein the mixing occurs for at least one hour.

115. (New) The method of claim 113, wherein the mixing occurs at a temperature of about 55 to about 75 °C.

116. (New) The method of claim 113, wherein the mixing is performed under vacuum.

117. (New) The method of claim 113, wherein the xanthum gum is added through the bottom of a vessel containing docusate sodium.

118. (New) The method of claim 113, further comprising cooling the first composition.

119. (New) The method of claim 118, further comprising mixing while cooling.

120. (New) The method of claim 118, wherein cooling is continued down to about 25 °C.

121. (New) The method of claim 118, further comprising cooling the first composition to a temperature of about 25 to about 30 °C.

122. (New) The method of claim 118, wherein the second composition is combined with the cooled first composition.

123. (New) The method of claim 105, further comprising combining the second composition under vacuum to the first composition.

124. (New) The method of claim 105, further comprising adjusting batch weight.

125. (New) The method of claim 105, wherein the first composition further comprises a polyalcohol.

126. (New) The method of claim 125, wherein the polyalcohol is added to the first composition while maintaining the composition at temperature of about 60 °C to about 70 °C.

127. (New) The method of claim 105, further comprising screening the combined first and second compositions.

128. (New) The method of claim 105, further comprising straining the combined first and second compositions.

129. (New) The method of claims 105, wherein the second composition is combined with the first composition at a pressure of about 7 to about 10 psi.

130. (New) A method for forming a flocculated suspension of megestrol acetate, comprising:

preparing a first composition containing docusate sodium and xanthum gum by mixing docusate sodium and xanthum gum at a temperature of about 55 to 75 °C,

cooling the first composition,

preparing a second composition containing micronized megestrol acetate,

combining the first and second compositions to form a flocculated suspension of megestrol acetate wherein about 90% of the floccules of megestrol acetate have a diameter of less than 28 to 50 microns, and

wherein the flocculated suspension does not simultaneously contain polysorbate and polyethylene glycol.

131. (New) A method for forming a flocculated suspension of megestrol acetate, comprising:

preparing a first composition containing docusate sodium and xanthum gum by mixing docusate sodium and xanthum gum at a temperature of about 55 to 75 °C,

combining glycerol with the first composition,

cooling the first composition,

preparing a second composition containing micronized megestrol acetate,

combining the first and second compositions to form a flocculated suspension of megestrol acetate, and

adjusting batch weight,

wherein about 90% of the floccules of megestrol acetate have a diameter of less than 28 to 50 microns and the flocculated suspension does not simultaneously contain polysorbate and polyethylene glycol.

132. (New) A method for forming a flocculated suspension of megestrol acetate, comprising:

preparing a first composition containing a polyoxyethylene wetting agent, a suspending agent, a buffer, and a preservative,

preparing a second composition containing micronized megestrol acetate,

combining the first and second compositions to form a flocculated suspension of megestrol acetate wherein the wetting agent is present in an amount such that about 90% of the floccules of megestrol acetate have a diameter of less than 12 to 50 microns, and

wherein the flocculated suspension does not simultaneously contain polysorbate and polyethylene glycol.

133. (New) The method of claim 132, wherein the suspending agent comprises carboxymethyl cellulose.

134. (New) The method of claim 132, wherein the buffer is sodium citrate and citric acid.

135. (New) The method of claim 132, wherein the preservative is sodium benzoate.

136. (New) The method of claim 132, further comprising mixing the combined first and second compositions.

137. (New) The method of claim 132, further comprising preparing the first composition by mixing the wetting agent with a suspending agent.

138. (New) The method of claim 137, wherein the mixing occurs for at least one hour.

139. (New) The method of claim 137, wherein the mixing occurs at a temperature of about 55 to about 75 °C.

140. (New) The method of claim 137, wherein the mixing is performed under vacuum.

141. (New) The method of claim 137, wherein the suspending agent is added through the bottom of a vessel containing the wetting agent.

142. (New) The method of claim 137, further comprising cooling the first composition.

143. (New) The method of claim 142, further comprising mixing while cooling.

144. (New) The method of claim 142, wherein cooling is continued down to about 25 °C.

145. (New) The method of claim 142, further comprising cooling the first composition to a temperature of about 25 to about 30 °C.

146. (New) The method of claim 142, wherein the second composition is combined with the cooled first composition.

147. (New) The method of claim 132, further comprising adding the second composition under vacuum to the first composition.

148. (New) The method of claim 132, further comprising adjusting batch weight.

149. (New) The method of claim 132, further comprising screening the combined first and second compositions.

150. (New) The method of claim 132, further comprising straining the combined first and second agent compositions.

151. (New) The method of claim 132, wherein the second composition is combined with the first composition at a pressure of about 7 to about 10 psi.

152. (New) A method for forming a flocculated suspension of megestrol acetate, comprising:

preparing a first composition containing a polyoxyethylene wetting agent, a microcrystalline cellulose and carboxymethyl cellulose suspending agent, a buffer, and a preservative,

preparing a second composition containing micronized megestrol acetate,

combining the first and second compositions to form a flocculated suspension of megestrol acetate wherein about 90% of the floccules of megestrol acetate have a diameter of less than 12 to 50 microns, and

wherein the flocculated suspension does not simultaneously contain polysorbate and polyethylene glycol.

153. (New) A method for forming a flocculated suspension of megestrol acetate, comprising:

preparing a first composition containing a polyoxyethylene wetting agent, a microcrystalline cellulose and carboxymethyl cellulose suspending agent, sodium benzoate, citric acid, and sodium citrate,

preparing a second composition containing micronized megestrol acetate,

combining the first and second compositions to form a flocculated suspension of megestrol acetate wherein about 90% of the floccules of megestrol acetate have a diameter of less than 21 to 50 microns, and

adjusting batch weight,

wherein the flocculated suspension does not contain polysorbate.